

Rule No. 3 of 2018
Violations and Penalties Schedule for Clinical and Commercial Activities

Dubai Healthcare City Authority - Regulatory

Effective January 1, 2018

RU/RL/004/01

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INTRODUCTION

Dubai Healthcare City Authority (DHCA) Regulations referred to herein do hereby issue rules and provisions pertaining to the violations related to Clinical and Commercial Activities within Dubai Healthcare City. DHCR shall be responsible for implementing this Rule.

This Rule shall be read together with:

- a) DHCA Law No. 9 of 2011
- b) DHCR Standard of violations management- Enforcement
- c) DHCR Policy and Procedure of violations management- Inspection
- d) DHCA Rules and Regulations defined in this document
- e) DHCA Rule No. 2 of 2016, Violations Schedule Related to Hygiene and Maintenance Standards for Properties and Public Areas

REGULATIONS

Regulations set out the governance framework under which registered companies, Licensees function in DHCC. All entities or persons (including but not limited to owners, contractors and operators) residing, working or operating within the DHCC shall comply with the relevant Regulations and applicable Rules, Policies, Standards and Guidelines.

DHCC Regulations are:

- Governing Regulation No. 1 of 2013
- Healthcare Professionals Regulation No. 2 of 2013
- Complementary and Alternative Medicine Professionals Regulation No. 3 of 2013
- Healthcare Operators Regulation No. 4 of 2013
- Education Regulation No. 5 of 2013
- Research Regulation No. 6 of 2013
- Health Data Protection Regulation No. 7 of 2013
- Company Regulation No. 8 of 2013
- Commercial Services Licensing Regulation No. 9 of 2013

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ARTICLE (1)

Definitions and Interpretations

1.1 Capitalized and abbreviation words in this Rule shall have the meaning indicated below:

Activity	means a business activity permitted to operate in DHCC
Authority	means Dubai Healthcare City Authority (DHCA)
DHCC	Dubai Healthcare City Free Zone
DHCR	Dubai Healthcare City Authority – Regulatory
Inspector	means an official of DHCR who is appointed by the Minister of Justice to act as a judicial officer or who is authorized by DHCR as an inspector
Healthcare Operator (HCO)	means a hospital, clinic, laboratory, pharmacy or other Entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies
Healthcare Professional (HCP)	means a Licensed Healthcare Professional, Licensed Complementary and Alternative Medicine Professional, a Licensed Healthcare Operator, an Approved Education Operator, an Approved Research Operator, a Licensed Commercial Company, or a Non-Clinical Operating Permit Holder
License	means a Healthcare Professional, Complementary and Alternative Medicine Professional, Healthcare Operator, Approved Education Operator, Approved Research Operator, Commercial Company licensed in DHCA or a Non-Clinical Operating Permit Holder
Licensing Regulations	means the Dubai Healthcare City Commercial Services Licensing Regulations No. 9 of 2013
Licensee	means the holder of a company registered and licensed under Dubai Healthcare City Authority
UAE	means the United Arab Emirates
Property	means facilities, buildings, structures or plots within the boundaries of the DHCC owned by investors or forming part of the DHCC master community
Public Areas	means areas, facilities or amenities beyond the boundaries of privately owned plots and areas that are open and accessible to people.
Rule	This rule No. 3 of 2018

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- 1.2 This Rule shall take effect on the date of its issuance.
- 1.3 Wherever in this Rule an obligation or duty is placed on a Licensee or otherwise a Licensee is authorized to do any act, then unless it is otherwise provided, such obligation, duty or act may be carried out by the Directors, Owners, Operators or Licensee.
- 1.4 References in this Rule to time periods are to be construed in accordance with the Gregorian calendar. Whenever in this Rule reference a period of time, such period will include every calendar day, except that:
- 1.5 When the last day of the period falls on a Friday or a Saturday, the period will end instead on the following Sunday; and
- 1.6 When the last day of the period falls on a UAE or Dubai public holiday, the period will end instead on the next day that is not a UAE or Dubai public holiday.
- 1.7 Unless the context otherwise requires, any reference in this Rule to a “person” includes a reference to a natural person, and to a corporate body, limited liability company, association or partnership and to the legal or personal representatives, legal successors and lawful assigns of any such person.
- 1.8 In the event of any inconsistency in this Rule or between this Rule and any other applicable law or regulation (whether issued by the Authority or otherwise), the Authority will determine the correct interpretation and each Licensee shall be so bound.
- 1.9 Any word(s) used in this Rule however not defined in the Definition shall have the meaning as contemplated under each respective Rules or Regulations

ARTICLE (2)

Purpose

- 2.1 All entities or persons (including but not limited to owners, contractors and operators) residing, working or operating within the DHCC are required to comply with all the rules and regulations issued by the DHCA from time to time. Ignorance of the rules and regulations excuses no one from the compliance therewith.

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ARTICLE (3)

Inspection

- 3.1 DHCR requires inspection of the Properties within DHCC from time to time to ensure compliance with DHCC Rules, Regulations, guidelines, requirements and relevant Federal Laws. DHCR reserves the right to enter the Property at any time without prior notice.
- 3.2 In case of serious violations or repeated incidents which may place people at risk or harm, the Authority may order the Property to be closed and or the License suspended or fully revoked, and all work or operations associated with such risk shall be stopped immediately until the corrective action is completed by the parties concerned.

ARTICLE (4)

Violations

- 4.1 All entities or persons (including but not limited to owners, contractors and operators) residing, working or operating within the DHCC in violation of the DHCC rules and regulations shall be guilty of an offence which, if not remedied to the satisfaction of the Authority, shall render entities or persons liable to sanctions as given in this section, or such other sanctions as the Authority may consider necessary from time to time.
- 4.2 Repeated violations will result in imposition of additional fines or freezing of services to the Licensee as deemed fit.
- 4.3 All incidents and accidents which occur at a Licensee's premises and which result in a person needing medical attention must be reported to the Authority within 24hours of the date of the incident/ accident.
- 4.4 Specific instructions received from Dubai Courts pertaining to the sponsored employees shall be executed by the authority.
- 4.5 Visa related violations are in accordance with DHCA Visa Policy.
- 4.6 Blacklisting/ Banning/ Suspension of the entry of the sponsored employee are at the sole discretion of the Authority.
- 4.7 Certain violations may be subject to additional penalties from other relevant authorities.

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Appendix 1: Violations Schedule – General

SR No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
1	*Late Renewal of Commercial License and Operating Permit (Per week after 30 days grace period)	LICENSEE	N/A	250	N/A
2	Operate the facility with expired Commercial license or operating permit (after 30 days grace period)	LICENSEE	N/A	2,000	4,000
3	Performing other than the permitted activities as registered in the commercial license, operating and or clinical permits.	LICENSEE	N/A	2,500	5,000
4	Non-commitment to the terms/conditions defined in the operating permit	LICENSEE	N/A	3,000	6,000
5	Non commitment to the undertaking submitted to Authority	LICENSEE	N/A	2,000	N/A
6	Practicing a business/clinical activity in an establishment closed by the authority	LICENSEE	N/A	10,000	20,000
7	Failure to provide DHCC access Card, Personal Identity or license permit during practice	LICENSEE	Notice	500	1,000
8	Failure to provide information or documents legitimately requested by DHCR within the specified timeframe	LICENSEE	N/A	2,000	4,000
9	**Providing incorrect, false, fraudulent, or misleading information in any application and/or document provided to DHCR	LICENSEE	N/A	10,000	20,000
10	Operate after hours without permission from DHCR (after 12:00 am)	LICENSEE	Notice	2,000	4,000
11	Failure to cooperate with the authorized inspector(s) or obstruct the inspection process.	LICENSEE	N/A	5,000	10,000
12	Display of materials, pictures or advertisements violating the public morality or ethics and/or Islamic traditions, culture or customs in United Arab Emirates.	LICENSEE	N/A	10,000	20,000
13	Distribution advertisement materials in public or private areas within DHCC without approval	LICENSEE	Notice	1,000	2,000
14	Operating without Commercial License and or Operating Permit	LICENSEE	N/A	5,000	N/A
15	Change or open an additional office for an existing license without permission	LICENSEE	N/A	2,000	4,000
16	Failure to comply with any applicable DHCR Regulation, Rule, Policy and standard or Federal Law not included herein.	LICENSEE	N/A	5,000	10,000

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**this violation may constitute a criminal offense under other applicable legislations in the UAE.

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Appendix 2: Violations Schedule Related to Commercial License

Sr. No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
1	Display products for sale by way of calling on the roads without a permit	LICENSEE	N/A	500	N/A
2	Displaying goods or provide services outside of the facility	LICENSEE	N/A	1,000	N/A
3	Presence of men in women's salons and/or women's fitness clubs and vice versa	LICENSEE	N/A	5,000	N/A
4	Organize conferences or exhibitions within DHCC without approval	LICENSEE	N/A	5,000	N/A
5	Establish business tents without a permit	LICENSEE	N/A	15,000	N/A
6	ATMs placed outside the bank or Vending machines without a permit	LICENSEE	N/A	3,000	N/A
7	Operation of restaurants, coffee shop, canteen, or any other food entity during Ramadan's fasting period operating without a permit.	LICENSEE	N/A	10,000	N/A
8	Store front facade Shading by more than 50% without permission	LICENSEE	N/A	250	N/A
9	Storing goods inside offices	LICENSEE	N/A	1,000	N/A
10	Placing kiosks/counters/cabinets for commercial purposes without permission	LICENSEE	N/A	2,000	N/A
11	Practicing a permitted business activity outside the registered establishment	LICENSEE	N/A	2,500	N/A
12	Installing lucky slot machines and other gambling games machines	LICENSEE	N/A	3,000	N/A
13	Organize and hold (a conference/exhibition) without a permission	LICENSEE	N/A	5,000	N/A
14	Sell promotional campaign tickets without permission	LICENSEE	N/A	5,000	N/A
15	Non-clinical facilities conducting clinical trials or research activity without valid permit from DHCR	LICENSEE	N/A	5,000	N/A
16	Delayed Annual Progress Report for Research (30 days from Annual Progress Report due date)	LICENSEE	N/A	2,000	N/A

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Appendix 3: Violations Schedule Related to Clinical Facilities and Healthcare Professionals in Dubai
Healthcare City

Sr. No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
1	Failure to display patient's rights and responsibilities document clearly in the facility	HCO	Notice	1,000	2,000
2	Failure to prominently display a copy of the facility Operating Permit	HCO	Notice	1,000	2,000
3	Failure of the Healthcare Operator to assign a suitably qualified Clinical/Medical director in the event of a vacancy of more than two months	HCO	Notice	2,000	5,000
4	Failure to notify DHCR prior to the temporary closure of the facility	HCO	N/A	5,000	N/A
5	Failure to notify DHCR prior to discontinuation of any clinical specialty/service	HCO	Notice	1000	2,000
6	Provision of unauthorized overnight patient stay in an outpatient facility	HCO	N/A	5,000	10,000
7	Failure to comply with DHCR medical records policy	HCO	N/A	1,000	2,000
8	Non-compliance to DHCC Health Data Protection Regulation	HCO/HCP	N/A	5,000	N/A
9	Non-compliance to DHCR Advertising Policy requirements	HCO/HCP	N/A	2,000	4,000
10	Falsification of information on a Clinical Operating Permit/Healthcare Professional License	HCO/HCP	N/A	10,000	20,000
11	Operation of a Healthcare Service with insufficient skilled healthcare professionals for the safe delivery of care	HCO	Notice	2,000	4,000
12	Failure to comply with the Policy for additional employment for HCP	HCO/HCP	N/A	2,000	4,000
13	Healthcare professional practicing without or with expired Basic Life Support certificate (BLS), Advanced Cardiovascular Life Support certificate (ACLS) and/or Pediatric Advanced Life Support (PALC) as applicable	HCO/HCP	N/A	2,000	4,000
14	Allowing a Physician/CAM Physician/Dentist to practice without license issued by DHCR	HCO	N/A	15,000	30,000
15	Allowing Nursing or Allied healthcare professional to practice without license issued by DHCR	HCO	N/A	5,000	10,000

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Sr. No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
16	Allowing healthcare professional to practice with expired/inactive license	HCO	N/A	2,000	4,000
17	*Late Renewal Fee of HCP license per month up to a maximum of six months (All categories)	HCP	N/A	500	N/A
18	Physician/CAM Physician/Dentist providing service(s) which is not within his/her license specialty or scope of practice	HCO/HCP	N/A	15,000	30,000
19	Nursing or Allied healthcare professional providing service(s) which is not within his/her license specialty or scope of practice	HCO/HCP	N/A	5,000	10,000
20	Practicing Healthcare profession without valid Medical Malpractice Insurance	HCO/HCP	N/A	5,000	10,000
21	Failure to issue electronic sick leave	HCO/HCP	N/A	2,000	4,000
22	Issue sick-leave for a period longer than the permitted for a healthcare professional	HCO/HCP	N/A	2,000	4,000
23	Issue sick leave for individual not attended the facility	HCO/HCP	N/A	10,000	20,000
24	Failure to comply with DHCR Pharmacy Standards	HCO	N/A	5,000	10,000
25	Pharmacy not adhering to the approved retail prices of the Ministry of Health and Prevention	HCO	N/A	2,000	4,000
26	Promote medicine(s) or medical products in a clinical facility	HCO	N/A	2,000	4,000
27	Pharmacies dispensing antibiotics without prescription	HCO	N/A	2,000	4,000
28	Unauthorized storage of narcotic drugs in the facility without approval from DHCR and MOHAP	HCO	N/A	20,000	40,000
29	Use, keep or dispense expired medications.	HCO	N/A	5,000	10,000
30	Use, keep or dispense unregistered medications without MOHAP approval	HCO	N/A	5,000	10,000
31	Conduct medical investigation/ checkups in the pharmacy	HCO	N/A	2,000	4,000
32	Failure to monitor the fridge or use the medical fridge for non-medical purpose	HCO	N/A	2,000	4,000

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Sr. No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
33	Failure to adhere to decisions issued by DHCR	HCO/HCP	N/A	5,000	10,000
34	Conduct research / clinical trials without a valid Research permit.	HCO	N/A	5,000	10,000
35	Conduct education activity without a valid Education permit	HCO	N/A	5,000	10,000
36	Conduct training courses and/or hands-on training on human subjects/volunteers prior to obtaining approval/accreditation from DHCR	HCO	N/A	2,000	4,000
37	Allowing a trainee to participate in a program without valid license.	HCO	N/A	2,000	4,000
38	Failure to notify DHCR of a Sentinel Event within the required timeframe.	HCO	N/A	2,000	4,000
39	Failure to perform periodic maintenance to a medical device/ equipment as per manufacturer's instructions	HCO	Notice	2,000	4,000
40	Failure to keep maintenance records of medical devices or equipment	HCO	Notice	2,000	4,000
41	Using unregistered/unapproved FDA, IEC or CE Medical Equipment	HCO	N/A	5,000	N/A
42	Failure to provide appropriate medical devices or materials required to provide clinical services	HCO	N/A	5,000	N/A
43	Failure to meet the requirements related to the management of medical waste and ways of disposal in accordance with DHCC HSE Approved Code of Practice	HCO	N/A	2,000	4,000

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Appendix 4: Violations Schedule Related to Visas

Sr. No	Violations	Applicability	1st Warning	Fine 1 (AED)	Fine 2 (AED)
1	Illegally employing personnel from other Licensees (per employee)	LICENSEE	N/A	5,000	N/A
2	Illegally employing persons who are not sponsored or approved by DHCA	LICENSEE	N/A	50,000	N/A
3	Supplying sponsored employees to work for third parties without approval	LICENSEE	N/A	5,000	N/A
4	Failure to apply absconder declaration for absence (in country) exceeding 14 continuous days	LICENSEE	N/A	1,000	N/A

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